609 252 4526

understood and that cancer treatment is an unpredictable art. However, the fact that one skilled in the art would have to engage in experimentation to determine which cancers could be successfully treated using the methods of the present invention does not render the claims unduly broad. Additionally, the fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation.

M.P.E.P. § 2164.01. The Federal Circuit states, "[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development." In re Brana, 34 USPQ2d 1436 (Fed. Cir. 1995). If pharmaceutical inventions were not patentable long before being optimized, the incentive to fully research and development vital drugs and potential cures in many crucial areas such as the treatment of cancer would be completely removed. Id. at 1443( emphasis added).

As acknowledged, the level of skill in the art of cancer treatment is high. The experimentation required to practice the present invention does not require more than the routine experimentation typically engaged in by the skilled oncologist. Accordingly, Applicants request withdrawal of the rejection.

## 35 U.S.C. 103(a)

Claims 1-5, 8 and 13 stand rejected under 35 U.S.C. 103 (a) as allegedly unpatentable over Bissery in view of Junji. Significantly, however, the cited references, either alone or in combination, do not suggest the specific combinations taught by the present invention. In fact, it is only with the benefit of hindsight provided by the present disclosure that one skilled in the art could expect a reasonable likelihood of success in practicing the present invention. In evaluating obviousness, one must look to see if "the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art." In re Dow Chemical Co. v. American Cyanamid Co., 837 F.2d 469, 471 (Fed. Cir. 1988). "Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure." Id. In this respect, the Patent Office Board of Appeals has held that, "an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force that would *Impel* one skilled in the art to do

ant has done." Ex parte Levengood, 28 U.S.P.Q.2d 1300, 1302

what the patent applicant has done." Ex parte Levengood, 28 U.S.P.Q.2d 1300, 1302 (pat. Off. Bd. App. 1993) (citations omitted; emphasis added).

Accordingly, Applicants believe that the present claims are in condition for allowance. An early Office Action to that effect is therefore, earnestly solicited.

If any fee is due in connection herewith, please charge such fee to Deposit Account No. 19-3880 of the undersigned. Furthermore, if any extension of time not already accounted for is required, such extension is hereby petitioned for, and it is requested that any fee due for said extension be charged to the above-stated Deposit Account.

Respectfully submitted,

Maureen Gibbons Attorney for Applicants Reg. No. 44,121

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000 (609) 252-3453

Date: May 28, 2003